IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF IOWA
CEDAR RAPIDS DIVISION

State of KANSAS, *ET AL.*, *Plaintiffs*, v. XAVIER BECERRA, *ET AL.*, *Defendants*.	Civil Action No. 1:24-cv-110

MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

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INTRODUCTION

The Centers for Medicare & Medicaid Services ("CMS") issued a Rule that imposes onerous minimum staffing standards and reporting requirements on nursing homes throughout the country. *See* "Medicare and Medicaid Programs; Minimum Staffing Standards for Long-Term Care Facilities and Medicaid Institutional Payment Transparency Reporting" ("the Rule"), 89 Fed. Reg. 40876 (May 10, 2024). Plaintiffs represent a diverse group of States and organizations with nursing homes as members. They ask this Court to enjoin and vacate the Rule, as it represents an existential threat to nursing homes around the country.

Nursing homes provide a valuable service to senior citizens whose families are unable care for them. Nursing homes that participate in Medicare must comply with the statutory requirements for "skilled nursing facilities" ("SNFs"), while those participating in Medicaid must meet similar requirements for "nursing facilities" ("NFs"), 42 U.S.C. § 1396r. *See* Plaintiffs' Statement of Undisputed Material Facts in Support of Their Motion for Summary Judgment ("SUMF") ¶2. Because the statutory requirements for both SNFs and NFs are largely parallel, these facilities are often collectively referred to as "long-term care" ("LTC") facilities. *See id.* ¶3. CMS has issued consolidated regulations applicable to all LTC facilities participating in Medicare and/or Medicaid. *Id.* ¶4.

In promulgating the Rule, CMS overstepped its statutory authority to force through mandatory minimum staffing requirements, at the expense of many LTCs' ability to continue to provide high-quality care for their residents. Since the nation is experiencing a drastic shortage of nurses, the Rule will cause many LTCs to shut down when they cannot meet the staffing mandate. And their vulnerable residents, whom the Rule purports to help, will be left to fend for themselves.

Congress has already set staffing requirements for LTCs participating in Medicare and

Medicaid: a minimum floor for registered nurses and a flexible, qualitative standard for other nurses. LTCs "must use the services of a registered professional nurse [("RN")] for at least 8 consecutive hours a day, 7 days a week." 42 U.S.C. § 1396r(b)(4)(C)(i); *id.* § 1395i-3(b)(4)(C)(i). And they must provide "24-hour licensed nursing services which are sufficient to meet the nursing needs of its residents." *Id.* § 1396r(b)(4)(C)(i); *id.* § 1395i-3(b)(4)(C)(i). For over fifty years, Congress and CMS maintained a flexible staffing standard and rejected proposals to replace it with a one-size-fits-all staffing requirement.

But last year, CMS abruptly changed course and imposed a universal standard: tripling the minimum hours for RNs, and setting quantitative ratios for nurses per hour per resident.[1] And they imposed a new "enhanced facility assessment" ("EFA") and transparency reporting requirements to move LTCs toward final compliance with the Rule. *See* 89 Fed. Reg. at 40,906. Essentially, the Rule abandons Congress's qualitative and flexible staffing standard and substitutes CMS's quantitative requirement which does not account for resident acuity or individual nursing home staff capacity.

The Rule is unlawful. CMS implemented a regulation that costs billions and upends an industry that affects millions of Americans each year. And it did so without clear congressional authorization, instead relying on vague "other" authority. This violates the major questions doctrine. If this "authority" means CMS can promulgate this Rule, our separation of powers has been severely undermined. By any standard, the Rule exceeds CMS's statutory authority. Congress already set minimum staffing standards that reject CMS's quantitative approach.

[1] The Rule requires (1) total nurse staffing of at least 3.48 hours per resident day ("HPRD"); (2) a mandate for RN staffing of at least 0.55 HPRD; and (3) nurse aid ("NA") staffing of at least 2.45 HPRD. 89 Fed. Reg. at 40877. HPRD is defined as the "total number of hours worked by each type of staff divided by the total number of residents as calculated by CMS." *Id.*

Finally, the Rule is arbitrary and capricious. CMS did not reasonably explain its sharp departure from past practice, nor did it reasonably consider reliance interests and important aspects of the problem.

Plaintiffs accordingly move the Court to issue a final judgment and grant summary judgment in favor of the Plaintiffs.

BACKGROUND

I. The statutory and regulatory background

A. Congress enacts statutes that specify staffing requirements for LTCs

In 1965, Congress established the Medicare and Medicaid programs by amending the Social Security Act. *See* Pub. L. No. 89-97, 79 Stat. 286 (July 30, 1965). LTCs participating in Medicare, 42 U.S.C. § 1395i-3, and Medicaid, 42 U.S.C. § 1396r are governed by largely parallel statutory requirements.[2]

These statutes require facilities to employ an RN for "at least 8 consecutive hours a day, 7 days a week," and provide 24-hour licensed nursing services that are "sufficient to meet the nursing needs of their residents." *Id.* § 1395i-3(b)(4)(C)(i) (Medicaid); *Id.* § 1396r(b)(4)(C)(i)(I)-(II) (Medicaid). They do not institute staffing quotas, and waivers are available to LTCs that struggle to hire the statutory minimum of nursing staff, but who can still provide adequate care to residents.

Under the Medicare statute, the Secretary is authorized to waive the requirement for LTC facilities to employ an RN for more than 40 hours per week if: (1) the facility is "located in a rural area and the supply of skilled nursing services is not sufficient to meet the needs" of local residents; (2) "the facility has one full-time [RN] who is regularly on duty at [the LTC] for 40

[2] Unless otherwise noted, arguments related to Medicaid facilities and requirements apply to Medicare facilities and requirements, and vice versa.

hours [per] week"; (3) the LTC facility has patients whose physicians have indicated that they do not require an RN or physician for 48 hours, or it has arranged for an RN or physician to provide necessary services when the full-time RN is not on duty; (4) "the Secretary provides notice of the waiver to the State long-term care ombudsman …"; and (5) the facility that is granted the waiver notifies residents and their families of the waiver. SUMF ¶7.

Under the Medicaid statute, a state may waive the staffing requirements for an LTC facility if: (1) the LTC facility demonstrates that, despite diligent efforts, it was unable to recruit appropriate personnel; (2) granting a waiver will not endanger the health or safety of the LTC facility's residents; (3) during times when an RN is unavailable, an RN or physician must be able to respond to calls from the LTC facility; (4) the state agency notifies the state long term care ombudsman of the waiver; and (5) the LTC facility informs its residents and family of the waiver. *See* 42 U.S.C. § 1396r(b)(4)(C)(ii)(I)-(V). Such waivers are subject to annual review by the State and the Secretary. *See* 42 U.S.C. § 1396r(b)(4)(C) ("Required nursing care"); SUMF ¶8. If a state is found to regularly grant waivers without facilities making diligent efforts to meet the statutory staffing requirements, the Secretary "shall assume and exercise the authority of the State to grant waivers." *Id.* ¶9.

B. Congress has rejected inflexible staffing mandates

The history of these statutory and regulatory requirements demonstrates that, until now, Congress and agencies have rejected CMS's new quantitative mandates.

After Congress amended the Social Security Act to declare that all LTC facilities participating in Medicare or Medicaid provide "24-hour nurse service[s] which is sufficient" to meet patient needs, including employing at least one RN full-time, Pub. L. No. 92-603, § 278, 86 Stat. 1329, 1424–27 (1972), it also introduced nurse-staffing waiver provisions for rural facilities under specific conditions, *see id.* § 267, 86 Stat. at 1450; SUMF ¶10. HHS's predecessor, through

its Social Security Administration ("SSA"), proposed regulations in 1973 that aligned with these statutory requirements. *See* 38 Fed. Reg. 18,620 (July 12, 1973); SUMF ¶11.

In the following decades, Congress and federal agencies repeatedly rejected attempts to impose any inflexible staffing mandate that would override these provisions. During the notice-and-comment period for the 1973 regulations, the SSA received comments urging it to deviate from Congress's flexible, qualitative approach to instead require a rigid nurse-to-patient ratio. *See* 39 Fed. Reg. 2,238, 2,239 (Jan. 17, 1974); SUMF ¶12. But the SSA refused, since "the variation from facility to facility in the composition of its nursing staff, physical layout, patient needs and the services necessary to meet those needs precludes setting [a specific ratio]." SUMF ¶14.

In 1980, HHS began directly administering the Medicare and Medicaid programs. The agency declined to implement specific staffing ratios when it proposed a "general revision" of relevant regulations. *See* 45 Fed. Reg. 47,368, 47,371, 47,387 (July 14, 1980); SUMF ¶¶15-17.

In 1987, Congress redefined nursing home categories and imposed the current staffing floor by requiring a registered nurse be on duty for at least eight hours per day, seven days a week. *See* Omnibus Budget Reconciliation Act of 1987, Pub. L. No. 100-203, § 4201(a), 101 Stat. 1330-161 (Dec. 22, 1987); *accord id.* § 4211(a), 101 Stat. 1330-186; SUMF ¶18. Congress included waiver provisions and commissioned studies to analyze staffing requirements—in particular "the appropriateness of establishing minimum caregiver to resident ratios." *See* Pub. L. No. 101-508, §§ 4008(h), 4801(a), 104 Stat. 1338 (Nov. 5, 1990); SUMF ¶19. But Congress did not implement mandatory ratios, and CMS continuously administered Congress's staffing standards without incident. *See* 42 C.F.R. § 483.35(a)–(b) (2016); SUMF ¶20.

In 2016, CMS once again dismissed the push for mandatory staffing ratios and a 24/7 RN requirement. *See* 81 Fed. Reg. 68,688, 68,754–56 (Oct. 4, 2016); SUMF ¶21. It concluded that a "one-size-fits-all approach" to staffing was "inappropriate" and that "mandatory ratios" and a

"24/7 RN presence" were concerning. *Id.* ¶22. Specifically, CMS expressed concerns about mandatory ratios and the 24/7 requirement because "LTC facilities [vary] in their structure and in their resident populations." *Id.* ¶23. CMS determined regulations should focus "on the skill sets and specific competencies of assigned staff to provide the nursing care that a resident needs rather than a static number of staff or hours of nursing care." 80 Fed. Reg. at 42,201; SUMF ¶24. And it warned that "establishing a specific number of staff or hours of nursing care could result in staffing to that number rather than to the needs of the resident population." *Id.* ¶25. CMS also found a 24/7 RN mandate "could negatively impact the development of innovative care options, particular[ly] in smaller, more home-like settings," and conceded that "geographic disparity in supply could make such a mandate particularly challenging in some rural and underserved areas." 81 Fed. Reg. at 68,755; SUMF ¶26.

As CMS acknowledged, there is "widespread variability in existing minimum staffing standards" adopted by 38 States and the District of Columbia. *Id.* ¶27. CMS found that obvious when it succinctly explained its rejection of the one-size-fits-all staffing requirement: "The care needs of each of these populations are different. Facilities range in size from the very small to the very large. The capabilities of these facilities are [] different." *Id.* ¶28.

Finally, in 2021, as part of the "Build Back Better" legislation, Congress considered amendments to the Social Security Act that would have imposed a 24/7 RN requirement at LTCs, and commissioned a report "on the appropriateness of establishing minimum staff to resident ratios for nursing staff."[3] These, too, were rejected.

[3] *See* Section 132000, Registered Professional Nurses, and section 30720, Nurse Staffing Requirements, respectively. Build Back Better Act, HR 5376, 117th Cong., 1st sess., Congressional Record 167, no. 201, daily ed. (November 18, 2021). Available at https://www.congress.gov/congressional-record/volume-167/issue-201/house-section/article/H6375-4.

II. The Rule

In February 2022, the Biden-Harris Administration departed from decades of practice to impose "reform" that would "establish a minimum nursing home staffing requirement."[4] SUMF ¶29. Accordingly, it directed CMS to determine the necessary level and type of staffing. *Id*

A. The Abt Study

To fulfill its directive, CMS contracted with Abt Associates to perform a "mixed-methods Nursing Home Staffing Study" as a party of CMS's goal of identifying a minimum staffing requirement. *Id.* ¶31. The Biden-Harris Administration's goal was to issue proposed rules establishing minimum staffing requirements by February 2023. *Id.* ¶32. So the Abt Study was "conducted on a compressed timeframe" with data collected between June and December 2022. *Id.* ¶33. It was completed and published in June 2023. *Id.* ¶34.

Consistent with the government's decades of prior practice, the Abt Study did "not identif[y] a minimum staffing level to ensure safe and quality care." *Id.* ¶35. Instead, it found that if a minimum staffing level was imposed, "[n]ursing homes [would] face barriers to hiring, primarily [with] workforce shortages and competition from staffing agencies." *Id.* ¶35. The mandate would require between 43 and 90 percent of nursing homes to add more staff, would cost up to $6.8 billion in compliance each year, and would increase annual total salaries per nursing home from as low as $316,000 to $693,000. *Id.* ¶37.

The Abt Study does not support new and more onerous quantitative staffing requirements. It did not conclude a minimum staffing requirement would result in definitive benefits. It provided data only for "potential" benefits. *Id.* ¶38(a). And it did not conclude that a

[4] The White House, *FACT SHEET: Protecting Seniors by Improving Safety and Quality of Care in the Nation's Nursing Homes* (Feb. 28, 2022), available at https://pfs2.acl.gov/strapib/assets/EJCC_CMS_Fact_Sheet_e1218a2030_cc09811bef.pdf.

minimum staffing requirement would provide better healthcare outcomes for residents. The literature it reviewed "underscored" that there was no "clear eviden[tiary] basis for setting a minimum staffing level." *Id.* ¶38(b). And it did not conclude that a federally mandated minimum staffing requirement could feasibly be implemented without considering variations in resident acuity, ongoing staffing shortages, compliance costs, and the diverse circumstances affecting quality patient care. *Id.* ¶38(c). The Study's inability to meaningfully support CMS's desired regulation makes sense: the government had previously and repeatedly rejected similar proposals. *Id.* ¶39.

Besides failing to support a universal minimum staffing requirement, the Abt Study had other shortcomings as well. *Id.* ¶40. The study showed a troubling disregard for the ongoing "national health care staff shortages" and "current hiring challenges" that present barriers to nursing homes—which would make compliance with a new federal staffing requirement impractical. *See* Abt Study at xxi. And it acknowledged but ultimately ignored several potential unintended consequences of a national minimum staffing requirement, including: (1) the possibility that many nursing homes might be unable to achieve the staffing levels; (2) LTC facilities could be limited in resident admissions because of staff-to-patient ratios; and (3) nursing homes might even close down entirely, thereby potentially reducing access to care. SUMF ¶41.

B. Promulgation of the Rule

CMS issued its proposed rule in September 2023. *See* 88 Fed. Reg. 61352 (Sept. 6, 2023); SUMF ¶42. Despite over 46,000 public comments—some of which warned CMS that its proposed rule exceeded its statutory authority, contravened Congress's decision on staffing standards, and failed to consider barriers to compliance (SUMF ¶43)—CMS moved forward with the Rule in May 2024. *See* 89 Fed. Reg. 40,876; SUMF ¶44.

CMS claimed its minimum staffing standard is supported by "literature evidence, analysis of staffing data and health outcomes, [and] discussions with residents, staff, and industry." *Id.* ¶45. But it could cite only the Abt Study, which it insisted, despite the text of the Study itself, had showed a staffing requirement was necessary. *Id.* ¶46. CMS conceded, however, that "[t]here is no clear, consistent, and universal methodology for setting specific minimum staffing standards," as evidenced by the 38 states and D.C. that have adopted their own nurse-to-patient ratios. *Id.* ¶47. Notwithstanding the variability across the minimum staffing requirements different states employ, the inconclusive determination of the Abt Study, or the consistent rejection of a one-size-fits-all staffing requirement for over fifty years, CMS published the Rule.

As support for its authority to issue the mandates, CMS relied on "various provisions" containing "separate authority." *See id.* at 40,879, 40,890–9. These include (1) sections 1395i-3(d)(4)(B) and 1396r(d)(4)(B), permitting the Secretary of HHS to impose "such other requirements relating to the health and safety of residents or relating to the physical facilities thereof as the Secretary may find necessary;" (2) sections 1395i-3(b)(2) and 1396r (b)(2), requiring LTCs to "provide services and activities to attain or maintain the highest practicable physical, mental, and psychological well-being of each resident in accordance with a written plan of care;" and (3) sections 1395i-3(b)(1)(A) and 1396r(b)(1)(A), requiring LTCs to "care for [their] residents in such a manner and in such an environment as will promote maintenance or enhancement of the quality of life of each resident," § 1395i-3(b)(1)(A); § 1396r(b)(1)(A). *See* SUMF ¶48.

C. The Rule's requirements

The Rule imposes two mandatory minimum-staffing requirements on LTC facilities. *Id.* ¶49. First, it triples the required hours per day of RN services as determined by Congress.

Specifically, it imposes a "24/7 requirement" requiring LTC facilities to have an RN "onsite 24 hours per day, for 7 days a week that is available to provide direct resident care." 89 Fed. Reg. at 40,997; SUMF ¶50.

Second, the Rule abandons Congress's flexible, qualitative requirement that facilities "provide 24-hour licensed nursing services which are sufficient to meet the nursing needs of its residents." *Id.* ¶52. Instead, the Rule requires that LTCs "meet or exceed a minimum of 3.48 [HPRD] for total nurse staffing," which must include a "minimum of 0.55 [HPRD] for [RNs]," and a "minimum of 2.45 [HPRD] for nurse aides." *Id.* ¶53. Previously, federal regulations mirrored Congress's qualitative requirements to keep nursing staff available 24-hours per day without specifying a quantitative staffing requirement. *See id.* ¶55.

The Rule also introduces a new, more stringent waiver that supplants the statutory waiver. It permits Medicare participants to qualify for a partial waiver of the 24/7 RN requirement, but not the HPRD requirements. *Id.* ¶¶56, 57. And it introduces a new "hardship exemption," which ostensibly allows partial relief from the 24/7 requirement and minimum HPRD requirements. *Id.* ¶58. To obtain the hardship exemption, though, LTC facilities must (1) prove a significant local shortage of health care staff; (2) demonstrate unsuccessful recruitment efforts despite offering competitive wages; (3) document financial expenditures on staffing relative to revenue; *and* (4) publicly disclose their exemption status. *Id.* ¶59. And even if granted, the exemption only gives an 8-hour reprieve from the 24/7 RN requirement, leaving facilities with the requirement to staff for at least 16 hours per day, 7 days per week. *Id.* ¶60.

Beyond staffing, the Rule requires LTC facilities to conduct a comprehensive evaluation of their facility, residents, staff, and resident families to determine staffing and other needs. *Id.* ¶61. In doing so, LTC facilities must ensure the "active involvement" of direct care staff and their representatives and "solicit and consider input" from residents, their representatives, and family

members. *Id.* ¶62. Compliance is a continual burden, as LTC facilities must "review and update" the EFA at least annually, although CMS did not provide clear guidance on when updates are "necessary." *Id.* ¶63. LTC facilities must also engage in "contingency planning," despite already having emergency plans in place. *Id.* ¶64.

States are similarly obligated to comply with new "institutional payment transparency reporting" requirements. *Id.* ¶66. To comply, States will incur costs to collect and post information on the percentage of Medicaid payments to LTCs that go to direct compensation services relative to administrative overhead costs. *Id.*

D. The staffing mandates' flaws

In promulgating the Rule, CMS failed to adequately explain why it departed from statute to impose the 24/7 RN requirement. Nowhere did the Abt Study suggest that LTC facilities should require an on-site RN 24 hours per day, 7 days per week. *Id.* ¶67. CMS also did not explain how it determined its 3.48, 0.55, or 2.45 HPRD requirements. *Id.* ¶68. Instead, it claimed that the 3.48, 0.55, and 2.45 HPRD levels "were developed using case-mix adjusted data sources." *Id.* ¶69. It also asserted the 0.55 and 2.45 levels, though not the 3.48 level, were discussed during the notice of proposed rulemaking. *Id.* ¶70.

In the notice of proposed rulemaking, CMS suggested that it proposed minimum staffing levels of 0.55 HPRD for RNs and 2.45 HPRD for NAs based on findings from the Abt Study, additional data sources, "two listening sessions," and literature reviews *Id.* ¶71. But the Abt Study did not substantiate those specific levels. *Id.* ¶72. CMS also failed to establish how the "review of existing literature" or other data assessments support the staffing levels. CMS provided no rationale for the 3.48 HPRD requirement in either the notice of proposed rulemaking or the Rule, aside from vaguely stating it was developed using "case-mix adjusted data sources." *Id.* ¶73.

CMS's minimum staffing ratios require LTC facilities to ignore the variability in resident acuity and needs. *Id.* ¶74. Some facilities with higher acuity residents may need greater staffing, while others with lower acuity residents may not require an RN present 24/7. CMS failed to explain why the same staffing is necessary at all facilities. *Id.* ¶75. And CMS failed to meaningfully consider the ongoing shortage of nursing staff across the country; it offered a mere $75 million to help "increase the [LTC] workforce" that it "expects" will be used for "tuition reimbursement." *Id.* ¶76. But $75 million is a minuscule fraction of what is needed to comply—$43 billion—meaning LTC facilities will be on the hook for the remainder. *Id.* ¶¶77, 78.

E. The Plaintiffs

Plaintiffs are twenty states, two LTC facilities, and seventeen non-profit organizations that represent LTC facility members in twenty-one states. Each is harmed by the Rule. The Rule itself projects compliance costs will exceed $5 billion per year after full implementation. *Id.* ¶79. Outside studies have placed the cost at more than $7 billion. *Id.* ¶80.

The Rule already imposes large financial and administrative burdens that will only increase as full implementation nears. For example, Wesley Commons, an LTC facility and member of Plaintiff LeadingAge South Carolina, hired two additional RNs to ensure it can comply with the EFA and 24/7 RN requirements, incurring extra costs of $14,650 (without considering night and weekend shifts). *See* Dkt. 30-20 at 5–6, App. 226-27. It also reinstated two full-time nursing assistants because of the HPRD requirement, incurring additional yearly costs of $66,560. *See id.* And its increased pay to retain and recruit staff is an additional $164,428 per year. *See id.* Many other LTC facilities are similarly engaged in advanced hiring, making staff changes, providing enhanced benefits, and increasing recruitment efforts now to ensure compliance. *See, e.g.*, Dkt. 30-10 at 7–9, App. 119-21; *See* Dkt. 30-20 at 7, App. 228; Dkt. 30-22 at 8–9, App. 243-44.

LTC facilities that have not already hired staff to comply with the Rule will do so soon. Those costs are significant burdens. And they are especially harmful in rural areas (where the required workforce simply does not exist) and in other tight labor markets. *See, e.g.*, Dkt. 30-11 at 7, App. 128 (Kansas needs an additional 312 RNs and 601 NAs to meet the minimum staffing ratios, on top of the existing 2,360 RN and 663 NA job openings); Dkt. 30-18 at 7–15, App. 200-08 (describing workforce shortages and additional yearly cost for Pennsylvania LTC facilities of over $689,000 *per provider*). Many nursing homes will be unable to absorb the costs as they rely on historically underfunded Medicaid and Medicare reimbursement while serving seniors who cannot otherwise afford the escalating cost of care.

LTC facilities that are motivated to provide sufficient care for their residents will incur substantial costs, and they may be required to rely on expensive temporary staffing agencies to fill gaps. Temporary staff may provide lower quality care because they are less familiar with and less invested in the residents' wellbeing. *See, e.g.*, Dkt. 30-16 at, App. 204; Dkt. 30-18 at 6, App. 222. But the Rule offers little choice, because it staffs to numbers, not needs. And the resulting increased costs will likely lead to reduced services and increased closures, shrinking long-term care availability for seniors and forcing many to facilities far from family and friends. *See, e.g.*, Dkt. 30-11 at 7– 10, App. 128-130; Dkt. 30-26 at 4–6, App. 273-75; Dkt. 30-18 at 7–15, App. 200-08; Dkt. 30-8 at 4–6, App. 102-04.

The Rule also harms Plaintiffs through its EFA requirement, *see, e.g.*, Dkt. 30-11 at 4–7, App 126-29, which imposes significant administrative burdens. CMS estimated it would cost each facility around $4,955. Many LTCs expect costs to be higher. For example, a LeadingAge Minnesota member has spent over $10,000 on administrative costs on an EFA without knowing whether it is compliant. Dkt. 30-14 at 3–4, App. 148-49. Plaintiff Dooley Center took about 16 hours to complete its EFA, approximately $579.36 per month to stay in compliance. Dkt. 30-25

at 3–5, App. 265-67. And Plaintiff Wesley Towers' EFA took 89 hours, thousands of dollars of staff time.[5] Dkt. 30-24 at 3–4, App. 258-59.

The State Plaintiffs that operate their own nursing homes subject to the Rule will incur all these same costs and burdens, with massively increased staffing costs, an inability to hire necessary staff such that they are forced to reduce services or even close, and increased staff time and costs devoted to EFAs that contain vague directives as to the requirements and frequency. *See, e.g.*, Dkt. 30-28 at 3, App. 283; Dkt. 30-2 at 2, 5, App. 68, 71. For example, Idaho estimates the Rule's staffing requirements alone will cost it at least $800,000 annually for each LTC facility. *See* Dkt. 30-2 at 3, App. 69.

State Plaintiffs' harms extend beyond their LTC facilities. For example, in Indiana, where compliance will cost well over $100 million, 89 Fed. Reg. at 40,962, tbl. 18; *id.* at 40984, tbl. 28, much of the cost will be passed on to State health plans. And each State will face increased costs through the Medicaid and Medicare programs. Minimum staffing requirements increase the cost of care, and although the federal government provides some reimbursement, it will not fully cover the costs. *See* Dkt. 30-5 at 5, App. 88; *see also* Dkt. 30-4 at 5–6, App. 81-82

The Rule also harms States by substantially increasing their administrative costs through the Rule's institutional payment transparency reporting requirements. *See* 89 Fed. Reg. at 40,995; *see also* Dkt. 30-4 at 3, App. 79; Dkt. 30-3 at 3, App. 75; Dkt. 30-7 at 3, App. 95. And States must maintain the reported information on a public website, which, CMS acknowledges, will cost the States at least $183,851 in the first year. 89 Fed. Reg. at 40,991; *see also, e.g.*, Dkt. 30-2 at 4, App. 70. And the States must process waiver requests and investigate complaints about

[5] Underscoring the arbitrariness of the staffing mandates, the EFAs from Dooley Center and Wesley Towers demonstrated there is no need for 24/7 RN coverage at their respective facilities. *See* Dkt. 30-25 at 3–5, App. 265-67; Dkt. 30-24 at 2–3, App. 257-58.

alleged noncompliance with the Rule, *see* Dkt. 30-2 at 2–4, App. 68-70; Dkt. 30-7 at 3–4, App. 95-96; Dkt. 30-4 at 3–5, App. 79-81, which are likely to occur given the shortage of trained nurses, *see* Dkt. 30-2 at 2–3, App. 68-69; Dkt. 30-5 at 2–3, App. 85-86.

LEGAL STANDARD

Summary judgment is appropriate when "there is no genuine issue as to any material fact and … the moving party is entitled to judgment as a matter of law." *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986) (quoting Fed. R. Civ. P. 56(a)). The party moving for summary judgment bears "the initial responsibility of informing the district court of the basis for its motion and identifying those portions of the record which show a lack of a genuine issue." *Hartnagel v. Norman*, 953 F.2d 394, 395 (8th Cir. 1992) (citing *Celotex*, 477 U.S. at 323). Once the moving party has met this burden, the non-moving party must go beyond the pleadings and identify specific facts showing that there is a genuine issue for trial. *Mosley v. City of Northwoods*, 415 F.3d 908, 910 (8th Cir. 2005). The non-movant must show an alleged issue of fact is genuine and material as it relates to the substantive law. If the non-movant fails to make that showing with respect to an essential element of a claim or defense on which it bears the burden of proof, then the moving party is entitled to judgment as a matter of law. *Celotex*, 477 U.S. at 322.

ARGUMENT

I. The Rule is unlawful

Under the Administrative Procedure Act (APA), a court "must hold unlawful and set aside agency action, findings, and conclusions" that are "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right," or "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law[.]" 5 U.S.C. § 706(2)(A)(C). The Rule (A) contradicts the statute and exceeds CMS's statutory authority, (B) violates the major questions

doctrine, and (C) is arbitrary and capricious. The Court should therefore grant judgment to the Plaintiffs and vacate the rule under the Administrative Procedure Act.

As a preliminary point, the Court does not owe any deference to CMS's interpretation of the statute. In *Loper Bright Enterprises v. Raimondo*, 144 S. Ct. 2244, 2273 (2024), the Supreme Court held that "courts need not and under the APA may not defer to an agency interpretation of the law simply because the statute is ambiguous." The court also recognized that if "the *best reading* of a statute is that it delegates authority to an agency, the role of the reviewing court under the APA is, as always, to independently interpret the statute and effectuate the will of Congress subject to constitutional limitations." *Id.* at 2263. Finally, the court stated, "statutory ambiguity…is not a reliable indicator of actual delegation of discretionary authority to agencies." *Id.* at 2272. In short, this Court cannot presume statutory delegation if the statute is ambiguous. It must determine the "best reading" of the statute in order to decide whether such delegation exists.

A. The Rule contradicts the statute and exceeds CMS's limited statutory authority

Any reading of the statute demonstrates that CMS does not have a plausible argument that Congress gave it the authority to implement the Rule. CMS, like all administrative agencies, is a "creature[] of statute," and accordingly "possess[es] only the authority that Congress has provided." *Nat'l Fed'n of Indep. Bus. v. Dep't of Labor,* 595 U.S. 109, 117 (2022). "[A]n agency literally has no power to act . . . unless and until Congress confers power upon it." *La. Pub. Serv. Comm'n v. FCC*, 476 U.S. 355, 374 (1986); *see also* 42 U.S.C. § 1302(a) (Secretary may not "publish rules and regulations" that are "inconsistent with" the law).

In promulgating the Rule, CMS relies on "miscellaneous" and "other" authority in the statute to contradict and exceed the specific limits that appear in the statutory sections dealing directly with nurse staffing at LTCs. The Rule is therefore unlawful. Moreover, any court that

accepted the breadth of CMS's authority, which would be required to justify the Rule, would cast constitutional doubt on the statute.

1. The Rule conflicts with statute

The Rule's conflict with the statute is the best evidence that it was not promulgated with clear authorization from Congress. The Medicare and Medicaid statutes speak directly to LTC staffing. LTC facilities "must use the services of a registered professional nurse for at least 8 consecutive hours a day, 7 days a week." 42 U.S.C. § 1396r(b)(4)(C)(i); *accord id.* §1395i-3(b)(4)(C)(i). And they must provide 24-hour nursing services "sufficient to meet the nursing needs of its residents." 42 U.S.C. § 1396r(b)(4)(C)(i); *accord id.* § 1395i-3(b)(4)(C)(i). There are no staffing ratios in the statute.

The Rule nevertheless replaces these statutory requirements with mandates that an LTC facility "must have a registered nurse (RN) onsite 24 hours per day, for 7 days a week" and must meet arbitrary staff-to-patient ratios. 89 Fed. Reg. at 40,997, 40,996. There is no specific statutory provision that authorizes this revision.

Additionally, the Rule's waiver provisions provide only an 8-hour per day exemption to the 24-hour required staffing. 89 Fed. Reg. at 40,953. This means that an LTC facility will never be allowed to have less than 16 hours of nursing staff per day. Congress, on the other hand, provides waivers even for its 8/7 requirement. *See* § 1396r(b)(4)(C)(ii); *accord* § 1395i-3(b)(4)(C)(ii). The Rule nullifies this statutory waiver.

"Agencies may play the sorcerer's apprentice but not the sorcerer himself." *Alexander v. Sandoval*, 532 U.S. 275, 291 (2001). The Rule is a crude attempt by CMS to play sorcerer. Congress considered LTC facility staffing and waivers, and it determined the only appropriate standards to enforce nationwide. Since the Rule conflicts with Congress's decision, it is unlawful.

2. **CMS lacks authority to impose the 24/7 RN and HPRD requirements**

Despite the Rule's conflicts with statute, CMS claims authority to "revise" the statutes on the basis of "miscellaneous" and "other" authority that appears elsewhere in the statute. *See* 89 Fed. Reg. at 40,898

The Supreme Court has also cautioned that courts should be especially skeptical of agency action when the agency uses "a wafer-thin reed on which to rest such sweeping power." *Ala. Ass'n of Realtors v. Dep't of Health & Human Servs.*, 594 U.S. 758, 765 (2021). And it is an elementary principle of statutory interpretation that Congress "does not alter fundamental details of a regulatory scheme in vague terms or ancillary provision—it does not, one might say, hide elephants in mouseholes."." *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 468 (2001). Yet that is precisely where CMS locates its authority for the Rule.

CMS disclaims reliance on the statutes that speak directly to staffing. *See* 89 Fed. Reg. at 40,891. It relies instead on "various provisions" elsewhere in the Social Security Act that apparently contain "separate authority." *Id.* at 40,879, 40,890–91. These include the statutory mandates that every LTC facility:

- meet "such other requirements relating to the health and safety of residents or relating to the physical facilities thereof as the Secretary may find necessary." 42 U.S.C. § 1396r(d)(4)(B), *accord id.* § 1395i-3(d)(4)(B);
- "provide services and activities to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident in accordance with a written plan of care," 42 U.S.C. § 1396r(b)(2), *accord id.* § 1395i-3(b)(2); and
- "care for its residents in such a manner and in such an environment as will promote maintenance or enhancement of the quality of life of each resident." 42 U.S.C. § 1396r(b)(1)(A); *accord id.* § 1395i-3(b)(1)(A).

None of these provides the authority CMS seeks. Indeed, the only provision that even arguably allows authority for CMS to engage in rulemaking at all requires LTCs to meet "*other* requirements relating to the health, safety, and well-being of residents or relating to the physical facilities thereof[.]" 42 U.S.C. § 1396r(d)(4)(B), *accord* 42 U.S.C. § 1395i-3(d)(4)(B) (emphasis added). This provision is under an "Other" subheading, which itself is under a "Miscellaneous" subheading, which itself is under "Requirements relating to administration and other matters." *Id.* CMS's use of this provision to justify the Rule is an example of "hid[ing] elephants in mouseholes." *Am. Trucking Ass'ns*, 531 U.S. at 468; *see also Dubin v. United States*, 599 U.S. 110, 120–21 (2023) (recognizing importance of considering headings in statutory interpretation); Antonin Scalia & Bryan A. Garner, *Reading Law: The Interpretation of Legal Texts* 221 (2012) (same).

As Congress addressed the minimum staffing requirements for LTCs in a separate statutory provision, it is not plausible that CMS obtained authority to alter that standard through rulemaking in a "miscellaneous" statutory provision. And "[g]eneral language" in one part of a statute "will not be held to apply to a matter specifically dealt with in another part of the same enactment." *See, e.g.*, *RadLAX Gateway Hotel, LLC v. Amalgamated Bank*, 566 U.S. 639, 645–46 (2012) (quoting *D. Ginsberg & Sons, Inc. v. Popkin*, 285 U.S. 204, 208 (1932)). The Rule is an inversion of that canon. CMS therefore exceeded its statutory authority in promulgating the Rule.

3. If upheld, the Rule raises constitutional doubt about the statute

CMS's only cited authority to promulgate the Rule is a gap-filling catchall. But if Congress intended to give CMS such vast power through that provision, its decision would call

into doubt that provision's constitutionality. CMS would have virtually no limits on what it could impose on LTCs in the name of resident "health and safety."

The constitutional doubt canon means this Court should interpret the Rule to avoid these severe constitutional problems. As the Supreme Court has explained, its "application of the nondelegation doctrine principally has been limited to the interpretation of statutory texts, and, more particularly, to giving narrow constructions to statutory delegations that might otherwise be thought to be unconstitutional." *Mistretta v. United States*, 488 U.S. 361, 373, n.7 (1989). The Supreme Court reads statutes with this principle in mind, *e.g.*, *Gundy v. United States*, 588 U.S. 128, 145–48 (2019), and this Court should too.

If Congress truly gave CMS the authority to implement a regulation that costs at least $43 billion in compliance and overrides specific statutes, then it supplied no intelligible principle guiding the exercise of that power. This presents serious nondelegation concerns that this Court should avoid by erring on the side of caution (*i.e.*, the separation of powers) and interpreting the statute narrowly. *See Kentucky v. Biden*, 23 F.4th 585, 607 n.14 (6th Cir. 2022) (rejecting "the government's interpretation" of a statute purportedly authorizing agency action in part because it "certainly would present non-delegation concerns").

B. The Rule violates the major questions doctrine

As shown, the Rule is not plausibly consistent with the Medicare and Medicaid statutes. But in this case, where the Rule has enormous economic and political significance and intrudes on state authority, even a plausible statutory justification is not enough. The major questions doctrine requires the Rule to be justified by clear congressional authorization. And that does not exist in the statute.

The major questions doctrine asks courts to use "common sense as to the manner in which Congress is likely to delegate a policy decision of such economic and political magnitude

to an administrative agency," *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000). Courts apply the major questions doctrine by first determining whether the agency action concerns a "major question," and then looking for clear congressional authorization. *E.g.*, *West Virginia v. EPA*, 597 U.S. 697, 746 (2022) (Gorsuch, J., concurring).

Agency action triggers the major questions doctrine when the agency "claims the power to resolve a matter of great political significance," when it "seeks to regulate a significant portion of the American economy," and "when the agency seeks to intrude into an area that is the particular domain of state law." *West Virginia*, 597 U.S. at 743-744 (Gorsuch, J., concurring) (internal citations omitted); *see also*, *e.g.*, *Biden v. Nebraska*, 143 S.Ct. 2355, 2375 (2023) (concluding doctrine applies to a "mass [student] debt cancellation program"); *West Virginia*, 597 U.S. at 724–25 (concluding doctrine applies to EPA regulation that would "substantially restructure the American energy market").

Courts apply the major-questions doctrine by first determining whether the agency action concerns a "major question," then looking for clear congressional authorization. *E.g.*, *Alab. Ass'n of Realtors*, 594 U.S. at 764 (finding no clear congressional authority for the CDC to issue a nationwide eviction moratorium).

1. The Rule triggers the major questions doctrine

The Rule's substantial cost and its nationwide upending of state regulation of LTCs have vast economic and political significance. CMS proposes to revamp the entire nursing home industry at a cost of at least $43 billion. The actual cost is likely much higher. That is similar to what the Supreme Court has found to trigger the major questions doctrine. *See id.* (finding $50 billion rule had "vast economic significance"). Moreover, the Rule also affects nearly all LTCs nationwide and will put many of them out of business. The economic and social consequences of mass LTC closures alone make this a major question. *See North Carolina Coastal Fisheries*

Reform Group v. Capt. Gatson LLC, 76 F.4th 291, 300 (4th Cir. 2023) (finding EPA bycatch rule to be a major question because the "economic and social consequences would be enormous").

Additionally, the Rule asserts federal control in an area of longstanding state authority, overriding existing minimum staffing laws in "nearly all states." 89 Fed. Reg. 40,877. Because Congress required only 8/7 RN staffing and allowed flexibility based on the needs of LTC facilities, States have added further requirements based on the needs of their residents and communities—the Rule acknowledges that 38 states and D.C. have adopted their own staffing standards that vary between them. *See* 89 Fed. Reg. at 40,881. As Justice Gorsuch observed in *West Virginia*, "When an agency claims the power to regulate vast swaths of American life, it not only risks intruding on Congress's power, it also risks intruding on powers reserved to the States." *West Virginia*, 597 U.S. at 744. (Gorsuch, J., concurring).

Due the Rule's impact on the nursing home industry, attendant significant cost, and displacement of States, it triggers the major questions doctrine.

2. Congress did not authorize the Rule

The Rule thus addresses major questions that should make any court "hesitate and look for clear congressional authorization before proceeding." *N.C. Coastal Fisheries*, 76 F.4th at 297. When a major question indicates that a court should be skeptical of agency action, Defendants have the burden of demonstrating that Congress gave them clear authorization to enact the Rule. *See West Virginia*, 142 S. Ct. at 732 (quoting *UARG v. EPA*, 573 U.S. 302, 324 (2014)); *see also Forest Serv. v. Cowpasture River Preservation Ass'n*, 590 U.S. 604, 621-22 (2020) ("Our precedents require Congress to enact exceedingly clear language if it wishes to significantly alter the balance between federal and state power…").

CMS lacks this clear authority. As discussed above, it relies exclusively on a decades-old, vague statutory grant. But "[i]t is unlikely that Congress will make an extraordinary grant of

regulatory authority through vague language in a long-extant statute." *West Virginia*, 597 U.S. at 747 (cleaned up). And the Court should be skeptical that Congress placed clear authorization for the Rule in the ancillary statutes where CMS claims to have found it.

Authorization is even less likely when, as here, the Rule's mandates conflict with other sections of the authorizing statute. *See id.* at 731 (rejecting agency action that Congress had already "considered and rejected"). Congress's decision, the "breadth of the authority" CMS now asserts, and the Rule's "economic and political significance" confirm that CMS cannot impose its mandates. *Id.* at 721. As demonstrated by its plain language, its location within the broader statutory scheme, and the relevant headings, the best reading of the statutes that CMS cites as authority is that they allow CMS to fill in administrative details concerning the health and safety of LTC facility patients not already covered by statute. They do not provide clear authorization for rewriting the statute's staffing provisions.

The Rule upends the nursing home industry and imposes billions of dollars in compliance costs. As CMS cannot meet its burden of showing clear authorization for its Rule, the Rule violates the major questions doctrine. This provides another basis on which the Court should conclude that CMS lacks statutory authority to enact the Rule.

* * *

In sum, the Rule conflicts with the statute and exceeds CMS's authority. And it violates the major questions doctrine. The Court should therefore grant summary judgment with respect to Counts I and II of Plaintiffs' complaint.

C. The Rule is arbitrary and capricious

The statutory arguments weigh heavily against the Rule. But it is also unlawful because it is arbitrary and capricious. The APA's arbitrary and capricious standard requires agency action to be "reasonable and reasonably explained." *E.g.*, *Texas v. United States*, 40 F.4th 205,

226 (5th Cir. 2022) (quoting *FCC v. Prometheus Radio Project*, 592 U.S. 414, 423 (2021)). The court "must set aside any action premised on reasoning that fails to account for relevant factors or evinces a clear error of judgment." *Id.*

An agency acts arbitrarily and capriciously when it departs sharply from prior practice without reasonable explanation or fails ignores alternatives to its action or the affected communities' reliance on the prior rule. *Dep't of Homeland Sec. v. Regents of the Univ. of Cal.*, 591 U.S. 1, 30 (2020). The standard is also met when an agency

> relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.

In re Operation of Mo. River Sys. Litig., 421 F.3d 618, 628 (8th Cir. 2005). Failing to account for costs is failure to consider an important part of the problem. *Michigan v. EPA*, 576 U.S. 743, 752-53 (2015). "Agencies have long treated cost as a centrally relevant factor when deciding whether to regulate. Consideration of cost reflects the understanding that reasonable regulation ordinarily requires paying attention to the advantages *and* the disadvantages of agency decisions." *Id.* And when an agency changes a longstanding policy, it must "show that there are good reasons for the new policy" and "be cognizant that longstanding policies may have 'engendered serious reliance interests that must be taken into account.'" *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 221-22 (2016) (quoting *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009)).

By promulgating the Rule, CMS arbitrarily and capriciously (1) engaged in a sharp departure from past practice without reasonable explanation, (2) failed to consider reliance interests, and (3) failed to consider important aspects of the problem.

1. Sharp departure from past practice

For 50 years, CMS consistently declined to deviate from the plain text of the statute by issuing staffing quotas. For example, in 1974, the Social Security Administration declined to adopt such a nationwide ratio requirement. Then, in 1980, HHS expressly declined to propose "any nursing staff ratios or minimum number of nursing hours per patient per day." *See also e.g.*, 45 Fed. Reg. at 47,371. A few years later in 1986, an HHS-commissioned study concluded that "prescribing simple staffing ratios is clearly inappropriate."[6] In 2002, the Secretary of HHS informed Congress that, after studying the issue for several years, it was not recommending the imposition of minimum-staffing ratios on LTC facilities.[7] Most recently, in 2016, CMS again rejected requests to adopt minimum-staffing rules, reiterating that it is not reasonable to adopt "a 'one size fits all' approach" toward LTC facilities. 81 Fed. Reg. at 68,755; *see id.* at 68,754-56, 68,758.

What happened to all of a sudden depart from this consistent past practice? Nothing meaningful. CMS used a single study that was commissioned solely as a pretext for doing what they wanted to anyway: impose new staffing mandates. Regardless, even that study did not justify the mandates they are now proposing. The cited study did "not identif[y] a minimum staffing level to ensure safe and quality care." *Id.* ¶35 (Abt Study at 115). Instead, it found that if a minimum staffing level was imposed, "[n]ursing homes [would] face barriers to hiring, primarily [with] workforce shortages and competition from staffing agencies." *Id.* ¶36 (Abt Study at xi).

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[6] *See* Inst. of Med., *Improving the Quality of Care in Nursing Homes* 102-03 (Mar. 1986), https://archive.ph/KFNCi.

[7] Letter from Tommy G. Thompson, Sec'y of Health & Human Servs., to J. Dennis Hastert, Speaker of House of Representatives 1 (Mar. 19, 2002) ("Thompson Letter"), reprinted in *Office of Asst. Sec'y for Planning & Evaluation, Dep't of Health & Human Servs., State Experiences with Minimum Nursing Staff Ratios for Nursing Facilities: Findings from Case Studies of Eight States* app. 1 (Nov. 2003), https://archive.ph/wip/KQWPt.

While an agency is free to depart from past practice, it must demonstrate there is good reason for doing so. *Encino Motorcars, LLC*, 579 U.S. at 221-22. One study that did not even conclude that the hiring mandates were appropriate or feasible does not cut it. This failure to reasonably explain sharply departing from 50 years of consistent practice is arbitrary and capricious.

2. Failure to consider reliance interests

Whether or not CMS reasonably explained its sharp departure from past practice, it is still obligated to consider reliance interests. It failed. In the decades that the flexible staffing mandate has been in place, states have responded by implementing staffing requirements tailored to their citizens' needs. In turn, LTCs have devoted considerable resources to meeting the state requirements and working with local lawmakers to achieve a workable standard and ensure that they are complying. CMS concedes that its 24/7 RN requirement imposes a one-size-fits-all requirement. 89 Fed. Reg. at 40,908. Such an approach is not only unworkable in a nation comprised of diverse states, but it also upends decades of an intentional balance by Congress to set the minimum standard that states may supplement.

A few examples exemplify the unique approaches that states have worked hard to adopt—given their individual circumstances and the realities of their workforce and budgetary landscape—to ensure that their senior citizens are appropriately protected:

- Kentucky does not set a numerical staffing requirement for nursing homes. Rather, Kentucky adopts a flexible approach requiring "twenty-four (24) hour nursing services with a sufficient number of nursing personnel on duty at all times to meet the total needs of residents." 902 Ky. Admin. Reg. 20:048, § 3(2)(a). Although Kentucky requires a charge nurse to be always on duty, a licensed practical nurse may serve in that role if a registered nurse is on call. *Id.* at § 2(10)(l).
- Missouri law requires skilled nursing facilities to have an RN on duty in the facility

for the day shift, and either an LPN or RN for both evening and night shifts. An RN also must be on call any time only an LPN is on duty. And all residential care facilities must have at least one employee for every forty residents. In addition, Missouri residential care facilities must employ a licensed nurse for eight hours per week per thirty residents to monitor each resident's condition and medication. 19 C.S.R. § 20-85.042; *id.* § 30-86.042 & .043.

- North Dakota has, for decades, set a minimum staffing requirement obligating facilities to have an RN on duty for eight hours per day. *See* N.D. Admin. Code § 33-07-03.2-14 (effective July 1, 1996). As of the first quarter of 2023, only *one* of North Dakota's 76 nursing facilities would comply with the Rule's new HPRD standards.
- West Virginia requires each nursing home in the State to have an RN on duty in the facility for at least eight consecutive hours, seven days a week. W. Va. Code R. § 64-13-8.14.4. If there is not an RN on duty, West Virginia law requires an RN to be on call. *Id.* § 64-13-8.14.5. West Virginia also requires nursing homes to provide at least "2.25 hours of nursing personnel time per resident per day." *Id.* § 64-13-8.14.1.

These varying standards sit alongside wide variations in circumstances within the different states. State Medicaid rates for nursing home services vary from $170 per day to over $400 per day. AHCA Cmt.6. Some states have a relatively steady supply of RNs and NAs, while many others are facing a massive shortage. *See, e.g.*, 89 Fed. Reg. at 40,957, 40,976; 81 Fed. Reg. at 6,755 (noting "geographic disparity in supply" of nursing staff). LTCs, and the States that oversee them, relied on the flexibility of the prior policy to establish laws and protocols suited to local conditions, balancing healthcare needs against operating costs and labor availability. Rather than considering how obliterating state and local flexibility would affect those reliance interests, CMS simply insisted that state variability "highlight[ed] the need for national

minimum staffing standards." 89 Fed. Reg. at 40,880; *cf* AHCA Cmt.6.

When an agency upends decades of state laws and practices that LTCs have relied on, it must seriously consider those reliance interests. *Encino Motorcars, LLC,* 579 U.S. at 221-22. CMS did not. It effectively ignored those interests by stating in general terms that increased staffing can lead to better outcomes for patients. The general proposition that increased staffing in understaffed facilities can lead to better outcomes is not a reasonable consideration of the reliance interests of both states and LTCs who have had flexibility for decades and have not been forced to engaged in "enhanced" assessments that may be inconsistent with both the Rule and the actual needs of their residents. Such a failure is arbitrary and capricious.

3. Failure to consider important aspects of the problem

Finally, the Rule is arbitrary and capricious because it fails to consider both the extreme difficulty of complying with the mandates and the staggering costs it puts on LTCs.

First, the Rule fails to consider the possibility that it may not be reasonably possible for many LTCs to comply with the Rule. The organizational and provider plaintiffs detail the hardship they already face in hiring staff and the impossibility of implementing the Rule's minimum staffing requirements because of the inadequate supply of RNs and NAs in their states and local communities. They further explain how the waivers and exemptions in the Rule provide no realistic assistance to their LTC facilities. And they explain how the EFAs are arbitrary and unduly burdensome. *See, e.g.*, Dkt. 30-18, ¶¶ 15-30, App. 200-207; Dkt. 30-20, ¶¶ 4-8, App. 224-30; Dkt. 30-11, ¶¶ 10-16, App. 128-32; Decl. 30-25, ¶ 9, App. 264-66; *see also* AHCA Cmt.1-2 5, 11-13, 18; Leading Age Cmt.1-2, 4. CMS barely acknowledges this issue, noting merely that the new requirements "exceed the existing minimum staffing requirements in nearly all States" and will require increased staffing "in more than 79 percent of nursing facilities nationwide." 89 Fed. Reg. at 40877.

CMS estimates that LTC facilities will need to hire an additional 15,906 additional RNs to meet the 24/7 RN requirement and 0.55 RN HPRD requirement (an increase of about 11.8%), plus an additional 77,611 NAs to meet the 2.45 NA HPRD requirement and 3.48 total nurse HPRD requirement (an increase of about 17.2%). *See id.* at 40958, 40,977-80. Those increases are unattainable at a time when many LTC facilities are already experiencing extreme difficulty finding qualified RNs and NAs to fill vacant positions, and when staffing shortages are expected only to worsen. *See generally* Dkt. 30-15, App. 165-177; Dkt. 30-11, App. 122-33; Dkt. 30-18, App. 200-16; Dkt. 30-20, App. 222-30; *see also, e.g.*, AHCA Cmt.5; LeadingAge Cmt.1. Put simply, "staffing mandates do not create more caregivers, nor do they drive caregivers to work in long term care." AHCA Cmt.1. The Rule also irrationally discounts the vital role of LPNs/LVNs, who hold nearly 230,000 jobs in LTC facilities across the country and undisputedly "provide important services to [their] residents." 89 Fed. Reg. at 40881; *see* Dkt. 30-11 ¶¶ 11, 14, App. 129-30, 131-32; Dkt. 30-8, ¶ 9, App. 104-05; Dkt. 30-14 ¶ 14, App. 160-161; AHCA Cmt.6; LeadingAge Cmt.2. As commenters pointed out, the Rule creates an incentive for LTC facilities "to terminate LPN/LVNs and replace them with . . . [less qualified] nurse aides" in order to meet the 2.45 NA HPRD requirement.

What was CMS' response to this mountain of evidence that many LTCs will not be able to comply with the Rule? It was an irrational conclusion that "[a] total nurse staffing standard will guard[] against" it. 89 Fed. Reg. at 40,893; *see* 88 Fed. Reg. at 61,366, 61,369. But that's obviously wrong. For example, a facility that already provides high-quality care through average staffing of 0.55 RN HPRD, 1.25 LVN/LPN HPRD, and 1.7 NA HPRD would satisfy the 3.48 total nurse HPRD requirement but would need an additional 0.75 NA HPRD to satisfy the 2.45 NA HPRD requirement. *See, e.g.*, Dkt. 30-25, ¶ 6, App. 263-64 (Dooley Center staffing includes 4.64 total nurse HPRD but it would have failed the Rule's required 0.55 RN HPRD 39% of the time).

The Rule pressures LTC facilities to replace experienced LPNs/LVNs with less-qualified new nurses to meet CMS's arbitrary quota of 2.45 NA HPRD.

The Rule does not deny that there are not nearly enough RNs and NAs available to enable future compliance by the 79 percent of LTC facilities that are not presently in compliance with the agency's new mandates. CMS asserts that the Rule's phase-in period will "allow all facilities the time needed to prepare and comply with the new requirements specifically to recruit, retain, and hire nurse staff as needed." 89 Fed. Reg. 40,894. But more time does not mean more nurses will suddenly become available. The Rule is a mandate that many LTC facilities will have no realistic way to meet. There is no reason to think that the shortage of RNs and NAs will ease over the next two to three years. In fact, it is projected to become even worse, as "hundreds of thousands are expected to retire or leave the health care profession entirely in the coming years." AHCA Cmt.5; *see id.* at 2 ("The phase-in provisions are frankly meaningless considering the growing caregiver shortage."); LeadingAge Cmt.7 (similar); *see also* Dkt. 30-18, ¶¶ 18-21, App. 202-04 (describing dire trends in healthcare workforce); Dkt. 30-11, ¶ 10, App 128-29 (similar); Dkt. 30-15, ¶ 7, App. 169-72 (similar). CMS asserts that it "fully expect[s] that LTC facilities will be able to meet [the Rule's] requirements," 89 Fed. Reg. at 40894, but the evidence provided by plaintiffs, and available to CMS during its rulemaking, shows this is not true.

CMS's "hardship exemption" does nothing to alleviate this. To start, such exemptions are available only to facilities that have already been surveyed and cited for failure to meet the new staffing standards—and "facilities cannot request" (or receive) "a survey specifically for the purpose of granting an exemption." 89 Fed. Reg. at 40,902. So instead of being able to proactively explain why it should be entitled to an exemption, facilities that cannot meet CMS's arbitrary requirements will face a perpetual risk of being sanctioned for non-compliance. *See* AHCA Cmt.6, 33-34; LeadingAge Cmt.6 (criticizing CMS's approach as "unnecessarily

punitive"). CMS repeatedly emphasizes that the hardship exemption is meant for "limited circumstances," 89 Fed. Reg. at 40,894, and that many facilities in areas of the country with severe shortages of available RNs and NAs would not qualify for an exemption because there are so many "other requirements" that must be met "to obtain an exemption." *Id.* at 40953. *See also, e.g.*, Dkt. 30-20, ¶ 7, App. 228-29 (describing unachievable nature of waiver and exemptions for LTC facilities); Dkt. 30-23, ¶ 9, App. 253-54 (similar); Dkt. 30-11, ¶ 16, App. 132 (similar). The complete lack of viable exemptions further demonstrates that CMS did not consider the virtual impossibility of LTCs increasing staff quotas at a time of nurse shortage.

Second, the Rule fails to reasonably consider the staggering costs. According to CMS, the Rule will cost over $5 billion per year to implement once fully phased in, *see* 89 Fed. Reg. at 40,949, 40,970. Other estimates place the costs as high as $7 billion per year, *see id.* at 40,950. The Rule does not provide any additional funding for Medicare or Medicaid, so CMS "assume[s] that LTC facilities . . . will bear the[se] costs." *Id.* at 40,949. LTC facilities are in no position to take on this huge financial burden. AHCA Cmt.5; LeadingAge Cmt.1-2; THCA Cmt.3. Almost 60 percent of LTC facilities already have negative operating margins; more than 500 LTC facilities closed over the course of the COVID-19 pandemic; and the costs associated with these new staffing mandates would likely force many more facilities to close. AHCA Cmt.5; *see* LeadingAge Cmt.1-2; *see also, e.g.*, Dkt. 30-11, ¶ 12, App. 130-31 (estimated costs for Kansas LTCs to comply with Rule on minimum staffing standards range between $64 million and $92.7 million in the first year, at an average annual cost of $211,905 per facility); Dkt. 30-8, ¶ 8, App. 102-03 (estimating total cost of $20 million for South Dakota facilities to comply with Rule).

CMS's imposition of this massive, unfunded staffing mandate, despite the ongoing workforce crisis and economic realities, is neither "reasonable" nor "reasonably explained." *Cf. Texas*, 40 F.4th at 226. It instead simply touts a new initiative that seeks to encourage people to

pursue careers in nursing by "investing over $75 million in financial incentives such as tuition reimbursement." 89 Fed. Reg. 40894. But this "one-time workforce effort" is "a drop in the bucket compared to the funding that will be needed to train [the] additional nursing staff" necessary to meet the new mandates. AHCA Cmt. 23; LeadingAge Cmt.1-2. It "is not going to fix the workforce crisis," and it does practically nothing to offset the $5 billion to $7 billion per year in costs that the Rule imposes on LTC facilities. AHCA Cmt.23; LeadingAge Cmt.1-2. This complete failure to consider the impact of *at least* $43 billion in regulatory costs on LTCs with almost no assistance from the federal government is arbitrary and capricious.

* * *

Plaintiffs have shown the Rule is arbitrary and capricious. The Court should therefore grant summary judgment with respect to Count III of Plaintiffs' complaint.

II. Scope of relief

A. Plaintiffs are entitled to vacatur, a permanent injunction, and declaratory relief

Under the APA, unlawful rules should be "set aside" and vacated. *See* 5 U.S.C. § 706; *see also Regents of the Univ. of Cal.*, 591 U.S. at 9 (unlawful agency action must "be vacated"); *Corner Post, Inc. v. Bd. of Governors of the Fed. Rsrv. Sys.*, 144 S. Ct. 2440, 2460 (2024) (Kavanaugh, J., concurring) ("[T]he APA authorizes vacatur of agency rules.").

Vacatur "operates to set aside a rule generally, not as a partial remedy for the plaintiffs." *Florida v. United States*, 660 F. Supp. 3d 1239, 1284 (N.D. Fla. 2023). Vacatur is not limited to the parties because, unlike an injunction, vacatur operates on the Rule itself—not the parties—by denying it legally operative effect and treating it as void as to all regulated parties. *See Career Colls. of Tex. v. U.S. Dep't of Educ.*, 98 F.4th 220, 255 (5th Cir. 2024) (vacatur under § 706 "should not be party restricted"); Mila Sohoni, *The Past and Future of Universal Vacatur*, 133 Yale L. J. 2305, 2311 (2024) ("The APA authorizes the universal vacatur of rules."); *see also*

Kiakombua v. Wolf, 498 F. Supp. 3d 1, 52 (D.D.C. 2020) (Jackson, J.) (vacatur of a rule "for everyone" is normal APA remedy).

Once vacated, a rule is "treated as though it had never happened." *Griffin v. HM Fla.-ORL, LLC*, 144 S. Ct. 1, 2 n.1 (2023) (Kavanaugh, J., statement respecting denial of application). Because vacatur removes the legal source of the agency's action, the agency cannot legitimately act unlawfully as to anyone. See Mila Sohoni, *The Power to Vacate a Rule,* 88 Geo. Wash. L. Rev. 1121, 1131 (2020); *e.g. Texas v. Becerra*, No. 6:24-cv-00211-JDK, ECF 41 (N.D. Tex. Aug. 30, 2024). CMS, like any agency, "literally has no power to act—including under its regulations— unless and until Congress authorizes it to do so by statute." *F.E.C. v. Cruz*, 596 U.S. 289, 301 (2022).

The Rule is an unlawful agency action. It should therefore be vacated.

B. The entire Rule is unlawful and should be vacated in its entirety

No part of the Rule is severable from the rest. The entire Rule serves to impose the staffing mandates that are unlawful and unauthorized by statute. And the entire Rule is arbitrary and capricious. The Court should therefore vacate the entire rule.

While the Rule contains a boilerplate severability clause, the presence of a severability clause in a rule is not the standard for determining severability. *See Mayor of Baltimore v. Azar*, 973 F.3d 258, 292 (4th Cir. 2020) (holding that a final rule was not severable despite the presence of a severability statement contained in the rule). Instead, this Court should consider whether CMS would have "adopted the [remaining] portion on its own." *North Carolina v. EPA*, 531 F.3d 896, 929 (D.C. Cir. 2008). And even if a severable part might have been adopted on its own, severance is inappropriate if severance would ultimately "impair the function" of the rule. *K Mart Corp. v. Cartier, Inc.*, 486 U.S. 281, 294 (1988). Here, no part of the Rule would have been adopted on its own, nor can any part function on its own.

At the preliminary injunction stage, the Court declined to issue a preliminary injunction

because it found that Plaintiffs were not likely to succeed on their challenge to the EFA requirement of the Rule, which irreparably harmed Plaintiffs. But the Court did not determine the EFA requirement was severable, or engage in any severability analysis. Dkt. 95 at 21 n.11, App. 371. That analysis will show that CMS cannot demonstrate that any part of the Rule would have been enacted on its own, without the rest of the Rule, or that the Rule would work without the unlawful staffing mandates.

The Rule is a single policy, in pursuit of one goal: to coerce LTCs into hiring additional staff. So the rest of the Rule, particularly the EFA and the transparency reporting requirements, are not separate provisions, unconnected to the staffing mandates. *See* SUMF ¶¶ 61-66. CMS itself described the EFA as "Phase 1" of a three-phase plan to implement the "final policy," where Phases 2 and 3 directly impose the staffing mandates. *See* 89 Fed. Reg. at 40,912. Elsewhere, the Rule requires LTC facilities to "use their facility assessment to develop and maintain a staffing plan to maximize recruitment and retention of nursing staff." 89 Fed. Reg. at 40,906. In short, the EFA is designed to move LTC facilities toward compliance with the Rule's minimum staffing requirements.[8] It would not have been adopted on its own, and the Rule would not function coherently with only "Phase 1" of the 3-Phase plan.

[8] *See, e.g.*, 89 Fed. Reg. at 40,881 ("[N]ational minimum staffing standards in LTC facilities and the adoption of a 24/7 RN and [EFA] requirements, will help to advance equitable, safe, and quality care sufficient to meet the nursing needs for all residents and greater consistency across facilities."); *id.* at 40,883 ("The [EFA requirements] . . . guard against any attempts by LTC facilities to treat the minimum staffing standards included here as a ceiling, rather than a floor."); *id.* at 40,906 ("We proposed at new § 483.71(b)(4) that LTC facilities would have to use their facility assessment to develop and maintain a staffing plan to maximize recruitment and retention of nursing staff."); *id.* (the EFA is "an important complement to the minimum staffing requirements."); *id.* at 40,909 ("The facility assessment is the foundation for LTC facilities to assess their resident population and determine the direct care staffing and other resources, to provide the required care to their residents.").

Similarly, the institutional transparency reporting requirement, which applies to States and their Medicaid programs, is intended to highlight where "understaffing" (i.e. noncompliance with the Rule) may be the result of excessive "non-compensation facility expenditures." *See* 89 Fed. Reg. at 40,916.[9] The transparency reporting thus forces the States—at State expense—to provide continuing data to CMS in order to justify the Rule's staffing mandates. It would not have been adopted, and the data would not be necessary, without the rest of the Rule.

Absent a severability determination, the entire Rule must be vacated if the staffing mandates are unlawful. Because the Rule makes clear that the EFA and institutional transparency reporting requirements are tied to the minimum staffing requirements, they should not be severed. Therefore, if the Rule's staffing mandates are unlawful, the entire Rule should be vacated.

CONCLUSION

For the foregoing reasons, Plaintiffs move this Court to grant Plaintiffs' motion for Summary Judgment, declare the Rule unlawful, and vacate the Rule.

[9] *See also id.* at 40,948 ("In response to concerns about the chronic understaffing... we proposed new Federal reporting requirements that are intended to promote public transparency."); *id.* at 40,991 ("We believe that gathering and sharing data about the amount of Medicaid payments going to the compensation of workers is a critical step in the larger effort to understand the ways we can enact future policies that support the institutional care workforce.").

Respectfully submitted,

KRIS W. KOBACH
Attorney General of Kansas

/s/ James R. Rodriguez
James R. Rodriguez, Kan. SC No. 29172*
Assistant Attorney General
Kansas Office of the Attorney General
120 SW 10th Ave, 2d Fl.
Topeka, Kansas 66612-1597
Phone: (785) 368-8197
Email: jay.rodriguez@ag.ks.gov
Counsel for Plaintiff State of Kansas

BRENNA BIRD
Attorney General of Iowa

/s/ Eric H. Wessan
Eric H. Wessan
Solicitor General
1305 E. Walnut Street
Des Moines, Iowa 50319
Phone: (515) 823-9117
Email: Eric.Wessan@ag.iowa.gov
Counsel for the State of Iowa

ALAN WILSON
Attorney General of South Carolina

/s/ Joseph D. Spate
Joseph D. Spate*
Assistant Deputy Solicitor General
Office of the South Carolina Attorney General
1000 Assembly Street
Columbia, South Carolina 29201
Phone: (803) 734-3371
Email: josephspate@scag.gov
Counsel for the State of South Carolina

STEVE MARSHALL
Alabama Attorney General

/s/ Edmund G. LaCour Jr.
Edmund G. LaCour Jr.*
Solicitor General
Office of the Attorney General
State of Alabama
501 Washington Avenue
P.O. Box 300152
Montgomery, Alabama 36130-0152
Phone: (334) 242-7300
Email: Edmund.LaCour@alabamaag.gov
Counsel for the State of Alabama

TREG TAYLOR
Attorney General of Alaska

Cori M. Mills
Deputy Attorney General of Alaska
/s/ Laura O. Russell
Laura O. Russell*
Alaska Bar No. 1311106
Assistant Attorney General
Alaska Department of Law
1031 West 4th Avenue, Suite 200
Anchorage, Alaska 99501-1994
Phone: (907) 269-5100
Email: laura.russell@alaska.gov
Counsel for the State of Alaska

TIM GRIFFIN
Arkansas Attorney General

/s/ Dylan L. Jacobs
Dylan L. Jacobs*
Deputy Solicitor General
Office of the Arkansas Attorney General
323 Center Street, Suite 200
Little Rock, AR 72201
Phone: (501) 682-2007
Email: Dylan.Jacobs@arkansasag.gov
Counsel for the State of Arkansas

ASHLEY MOODY
Florida Attorney General

/s/ Caleb Stephens
Caleb Stephens*
Assistant Solicitor General
Allen Huang
Deputy Solicitor General
Office of the Attorney General
The Capitol, Pl-01
Tallahassee, Florida 32399-1050
Phone: (850) 414-3300
Email: Caleb.Stephens@myfloridalegal.com
Allen.Huang@myfloridalegal.com
Counsel for the State of Florida

CHRISTOPHER M. CARR
Attorney General of Georgia

/s/ Stephen J. Petrany
Stephen J. Petrany*
Solicitor General
Office of the Attorney General
40 Capitol Square, SW
Atlanta, Georgia 30334
Phone: (404) 458-3408
Email: spetrany@law.ga.gov
Counsel for the State of Georgia

RAÚL R. LABRADOR
Attorney General of Idaho

/s/ Nathan S. Downey
Nathan S. Downey*
David H. Leroy Fellow
Office of the Attorney General
PO Box 83720,
Boise, Idaho 83720
Phone: (208) 334-2400
Email: Nathan.Downey@ag.idaho.gov
Counsel for the State of Idaho

THEODORE E. ROKITA
Attorney General of Indiana

/s/ James A. Barta
James A. Barta*
Solicitor General
Indiana Attorney General's Office
IGCS – 5th Floor
302 W. Washington St.
Indianapolis, IN 46204
Phone: (317) 232-0709
Email: james.barta@atg.in.gov
Counsel for the State of Indiana

RUSSELL COLEMAN
Attorney General of Kentucky

/s/ Aaron J. Silletto
Aaron J. Silletto*
Victor B. Maddox*
Jeremy J. Sylvester
Zachary M. Zimmerer
Kentucky Office of the Attorney General
700 Capital Avenue, Suite 118
Frankfort, Kentucky 40601
Phone: (502) 696-5300
Email: Victor.Maddox@ky.gov
Aaron.Silletto@ky.gov
Jeremy.Sylvester@ky.gov
Zachary.Zimmerer@ky.gov
Counsel for the Commonwealth of Kentucky

ANDREW BAILEY
Attorney General of Missouri

/s/ *Victoria S. Lowell*
Victoria S. Lowell,* 76461 MO
Assistant Attorney General
Office of the Missouri Attorney General
Missouri Attorney General's Office
815 Olive Street, Suite 200
St. Louis, Missouri 63101
Phone: (314) 340-4792
Email: Victoria.lowell@ago.mo.gov
Counsel for the State of Missouri

AUSTIN KNUDSEN
Attorney General of Montana

/s/ Peter M. Torstensen, Jr.
Peter M. Torstensen, Jr.*
Deputy Solicitor General
Montana Department of Justice
215 North Sanders
P.O. Box 201401
Helena, Montana 59620-1401
Phone: (406) 444.2026
Email: peter.torstensen@mt.gov
Counsel for the State of Montana

MICHAEL T. HILGERS
Attorney General of Nebraska

/s/ Zachary B. Pohlman
Zachary B. Pohlman*
Assistant Solicitor General
Office of the Nebraska Attorney General
2115 State Capitol
Lincoln, Nebraska 68509
Phone: (402) 471-2682
Email: Zachary.Pohlman@Nebraska.gov
Counsel for the State of Nebraska

GENTNER DRUMMOND
Attorney General of Oklahoma

/s/ *Garry M. Gaskins*
Garry M. Gaskins, II, OBA # 20212*
Solicitor General
Office of Attorney General
State of Oklahoma
313 N.E. 21st St.
Oklahoma City, OK 73105
Phone: (405) 521-3921
Garry.Gaskins@oag.ok.gov
Counsel for the State of Oklahoma

DREW H. WRIGLEY
North Dakota Attorney General

/s/ Philip Axt
Philip Axt*
Solicitor General
Office of Attorney General
600 E. Boulevard Ave Dept. 125
Bismarck, North Dakota 58505
Phone: (701) 328-2210
Email: pjaxt@nd.gov
Counsel for the State of North Dakota

MARTY J. JACKLEY
Attorney General of South Dakota

/s/ Megan Borchert
Megan Borchert*
Assistant Attorney General
Office of the Attorney General
State of South Dakota
1302 E. Hwy. 14, Suite #1
Pierre, South Dakota 57501
Phone: (605) 773-3215
Email: Megan.Borchert@state.sd.us
Counsel for the State of South Dakota

SEAN D. REYES
Attorney General of Utah

/s/ Stephanie M. Saperstein
Stephanie M. Saperstein*
Assistant Attorney General
Office of Utah Attorney General
195 North 1950 West
Salt Lake City, Utah 84116
Phone: (801) 680-7690
Email: stephaniesaperstein@agutah.gov
Counsel for Plaintiff State of Utah

JASON S. MIYARES
Attorney General of Virginia

/s/ Kevin M. Gallagher
Kevin M. Gallagher*
Principal Deputy Solicitor General
Virginia Office of the Attorney General
202 North 9th Street
Richmond, Virginia 23219
Phone: (804) 786-2071
Fax: (804) 786-1991
Email: kgallagher@oag.state.va.us
Counsel for the Commonwealth of Virginia

PATRICK MORRISEY
Attorney General of West Virginia

/s/ Michael R. Williams
Michael R. Williams*
Solicitor General
Office of the Attorney General of
West Virginia
State Capitol Complex
Building 1, Room E-26
Charleston, WV 25301
Phone: (304) 558-2021
Email: michael.r.williams@wvago.gov
Counsel for Plaintiff State
of West Virginia

/s/ Anna St. John
Anna St. John*
Hamilton Lincoln Law Institute
1629 K St. NW Suite 300
Washington, DC 20006
(917) 327-2392
anna.stjohn@hlli.org
Counsel for Plaintiffs LeadingAge Kansas, LeadingAge South Carolina, LeadingAge Iowa, LeadingAge Colorado, LeadingAge Maryland, LeadingAge Michigan, LeadingAge Minnesota, LeadingAge Missouri, LeadingAge Nebraska, LeadingAge New Jersey/Delaware, LeadingAge Ohio, LeadingAge Oklahoma, LeadingAge PA, South Dakota Association Of Healthcare Organizations, LeadingAge Southeast, LeadingAge Tennessee, LeadingAge Virginia, Dooley Center, Wesley Towers

**Pro Hac Vice*